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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,492	02/07/2006	Graziano Castaldi	2503-1196	9979
466	7590	09/12/2007		
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			EXAMINER SHAMEEM, GOLAM M	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 09/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,492

Applicant(s)

CASTALDI ET AL.

Examiner

Golam M. M. Shameem, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 14 and 16-20 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/07/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

This application is a 371 of PCT/EP04/08576 07/30/2004 is acknowledged.

Status of Claims

Claims 1-14 and 16-20 are currently pending in the application. Claims 17-20 have been added. Claim 15 was canceled.

Receipt is acknowledged of amendment / response filed on August 03, 2007 and that has been entered.

Claims 1-10 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

Information Disclosure Statement

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 02/07/2006, which has been entered in the file.

Response to Election/Restriction

In response to the restriction requirements, Applicants have elected Group V, which includes claims 13, 14 and 16 drawn to a method of use of a compound of formula V with traverse is acknowledged. Applicant's arguments (to withdraw restriction among Groups 1-V) have been fully considered and found partially persuasive and therefore, Examiner has agreed to modify the restriction requirements to include and examine Group IV claims 11 and 12 and also to rejoin the newly added claims 17-20 together with the elected invention of Group V, because they fall within the scope of the elected invention.

However, the Examiner respectfully disagrees with the Applicant's other arguments at this time because the Invention groups I-III differ materially in structure and in element from each other and therefore, are capable of supporting their own patents. The invention Groups I-V each relate to a set of structurally diverse and dissimilar compounds [having different variable groups, which are attached directly and indirectly to the core formula], process of preparing compounds, and their method of uses, which do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious. The core does not define a contribution over the art. The ring structure of formula V is further substituted by different variables such R, R₂, and R₃ etc, which are broadly defined and when the compound of formula V is taken as a whole, a plethora of vastly different compounds are possible. Thus these features are not considered 'special technical features' under PCT rules 13.1 and 13.2. Hence, the unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

In addition, 35 U.S.C. 372 (b)(2) clearly states that unity of invention may be reexamined under 35 U.S.C. 121. Restriction was based on PCT Rule 13.1, 13.2 and Annex B part 1(b) together with 37 CFR 1.475 and 1.499 for lacking unity of invention because of lacking a significant structural element qualifying as the special technical features.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B (2)(V) when dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the Examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised. If the Examiner finds one of the inventions unpatentable over the prior art the evidence or admission may be used in a rejection under 35 U.S.C. 103 (a) of the other invention. For these reasons, Applicant's arguments are found unpersuasive and, since 35 U.S.C. 101 allows one patent per invention, the requirement for restriction (election of species) is still deemed sound and proper.

Applicants preserve their right to file a divisional on the non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claim in the subject matter, which the applicant regards as his invention.

Claims 13, 14 and 16-20, are rejected under 35 USC § 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expressions "A method of using a compound" and "preparing the compound of formula (I) from a compound of formula (V)" [recited in claims 13 and 16, lines 1-5] render the claims indefinite because it is unclear from the claims what the Applicant is intending to encompass with these expressions and therefore, it is not possible to ascertain the metes and bounds of the claimed subject matter. Claims 13, 14 and 16-20 are

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rejected as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The steps leading to the preparation of a compound of formula (I) are not recited in the claims. The omission of failing to describe the claimed invention renders the claims incomplete. It is suggested that the essential step(s) for the preparation of a compound of formula (I), [such as described in claim 17], be incorporated in claims 13 and 16 or to amend the claims within the context and scope of the claims in order to overcome the rejection.

Objections

Claims 11 and 12 are objected to as being dependent upon a withdrawn base claim 1, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golem Shamed, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Tuesday-Friday from 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone number for this Group is 571-273-8300.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft

documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

Golam M. M. Shameem, Ph.D.
Primary Examiner
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GOLAM M. M. SHAMEEM, PH.D
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